

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 05 APR 2006

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Applicant's or agent's file reference 60342WO003		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/US2004/042455		International filing date (day/month/year) 17.12.2004	Priority date (day/month/year) 30.12.2003	
International Patent Classification (IPC) or national classification and IPC INV. G01N29/02 B01L3/00				
Applicant 3M INNOVATIVE PROPERTIES COMPANY				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 11 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 8 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in Item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains Indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 01.12.2005		Date of completion of this report 05.04.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized officer Tiede, R Telephone No. +31 70 340-1090		



**INTERNATIONAL PRELIMINARY REPORT
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International application No.
PCT/US2004/042455

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-35 as originally filed

Claims, Numbers

1-36 received on 01.12.2005 with letter of 01.12.2005

Drawings, Sheets

1/10-10/10 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☒ the claims, Nos. 37-40
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 10-16, 20-24

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 11-16, 20-24

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1, 19 (part); 2-9, 17,18, 20, 25-36 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	17,18,25-36
	No: Claims	1, 19 (part); 2-9, 20
Inventive step (IS)	Yes: Claims	17,18,25-36
	No: Claims	1, 19 (part); 2-9, 20
Industrial applicability (IA)	Yes: Claims	1, 19 (part); 2-9, 17,18, 20, 25-36
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY REPORT
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV.

There are 8 independent claims:

Claim 1: A detection cartridge comprising a housing, a sensor, a detection chamber with a flow front control feature, and a waste chamber

Claim 16: A detection cartridge comprising a housing, a sensor, a detection chamber with a flow front control feature, and a waste chamber, further comprising absorbent material and a capillary structure

Claim 17: A detection cartridge comprising a housing, a sensor, a detection chamber with a flow front control feature, and a waste chamber, further comprising module ports connected with them one or more sealed modules comprising a housing, an exit seal, a first chamber, a second chamber, an inter-chamber seal, and a plunger

Claim 19: Method of moving a sample material through a cartridge of claim 1

Claim 25: A sealed module comprising a housing, an exit seal, a first chamber, a second chamber, an inter-chamber seal, and a plunger

Claim 30: Method of delivering materials using a sealed module of claim 27

Claim 32: A module comprising a housing, an exit seal, a chamber, a plunger, and an input port

It appears that within these independent claims unity does not exist for the following reasons:

A) The "same" or "corresponding" technical features between these independent claims are that all claims relate to handling of material, a housing and chambers,

These features are already well known, e.g. see D1:US6156270 where a detection cartridge is disclosed comprising a housing (fig. 1, ref. 8, 9, col. 7, lines 31-50), a sensor (col. 15, lines 44-63; col. 7, lines 4-18), a detection chamber (fig. 1, ref. 6) with a flow front control feature such as channels in the opposing surface of the detection chamber (fig. 1, ref 6; col. 17, lines 1-14; col. 17, line 55 to col. 18, line 67; col. 23, line 6-36), and a waste chamber (fig. 1, ref. 7; col. 7, lines 31-50; col. 20, line 42 to col. 21, line 24).

Therefore, non of these features is a special (new and inventive) technical feature. Thus, no "same" or "corresponding" special technical features could be found between the independent claims 1, 17, 18, 21, 27, 33 and 35 as required by Rule 13.2 PCT.

Furthermore, D1 discloses all technical of claim 1 and thus subject-matter of claim 1 is not novel. Consequently, also all technical features common to only the subgroup of independent claims relating to a detection cartridge, ie. claims 1, 17 and 18 (see citations given above), are also disclosed in D1.

B) Also the common problem underlying the invention, to enhance the control of a flow of a liquid (description page 13), is already known, see D1 (eg. col. 14, line 43 to col 18, line 67 and col. 2, lines 6-12). Also the problem common to only a part of said claims to control the flow front (also page 13) is already known from D1 and solved in the same way as in claim 1 (see citations as given above for D1).

No other common problem could be found which could serve as the general inventive concept required by Rule 13.1 PCT.

Consequently, these claims are not unitary according to Rule 13 PCT.

C) If an independent claim does not avoid prior art, then the question whether there is still an inventive link between the dependent claims needs to be considered (see PCT administrative instructions Annex B, part 1(c)(ii)).

Three groups of claims directly depending on claim 1 could be identified:

Claims 2-9, relating to flow front control means, solving the problem to find alternative embodiments for flow front control means (description, page 13-19)

Claims 10-14, relating to details of the waste chamber, solving the problem to allow waste collection after the liquid passed the detection chamber (description, page 23-27)

Claim 15 relating to a fluid monitor, solving the problem to monitor the fluid flow (description, page 20)

Neither common technical features nor common problems over those discussed already in sections A and B could be identified for these groups of dependent claims. Consequently, these groups of claims are not unitary according to Rule 13 PCT.

C) Thus, the application is split into 4 groups of (alleged) inventions:

Group I: Claims 1 and 19 (part), 2-9, 20

A detection cartridge and method of use comprising a housing, a sensor, a detection chamber with a flow front control feature, and a waste chamber and details about said flow front control means, solving the problem to find alternative embodiments for flow front control means

Group II: Claims 1 and 19 (part), 10-14, 16, 21-24

A detection cartridge and method of use comprising a housing, a sensor, a detection chamber with a flow front control feature, and a waste chamber and details about said waste chamber, solving the problem to allow waste collection after the liquid passed the detection chamber

Group III: Claims 1 (part), 15

A detection cartridge and a method of use comprising a housing, a sensor, a detection chamber with a flow front control feature, and a waste chamber and a fluid monitor, solving the problem to monitor the fluid flow

Group IV: Claims 18, 25-36

A module comprising a housing, an exit seal, a chamber, a plunger, and an input port and a method to use said module, solving the problem to deliver reagents or other materials

Independent claim 16, which is not unitarian with claim 1, seems to relate to similar or the same problems as dependent claims 10-14. Consequently, these claims have been grouped together.

Only groups I and IV were searched by the ISA. Consequently, the following sections V and VIII will only address groups I and IV.

Re Item V.

Reference is made to the following documents:

- D1: US-A-6 156 270 (BUECHLER ET AL) 5 December 2000 (2000-12-05)
- D2: US-A-4 233 029 (COLUMBUS ET AL) 11 November 1980 (1980-11-11)
- D3: US-B1-6 656 428 (CLARK DAVID D ET AL) 2 December 2003 (2003-12-02)
- D4: GB-A-1 130 593 (NOVO TERAPEUTISK LABORATORIUM A/S) 16 October 1968 (1968-10-16)

**INTERNATIONAL PRELIMINARY
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(SEPARATE SHEET)**

International application No.

PCT/US2004/042455

D5: WO 02/088296 A (BOSTON BIOMEDICA, INC; SCHUMACHER, RICHARD, T;
TAO, FENG; LAWRENCE, NA) 7 November 2002 (2002-11-07)
D6: FR-A-2 612 297 (PASTEUR DIAGNOSTICS) 16 September 1988 (1988-09-16)

Group I:

- 1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 19 is not new in the sense of Article 33(2) PCT. Document D1 discloses a detection cartridge and its use comprising a housing (fig. 1, ref. 8, 9, col. 7, lines 31-50), a sensor (col. 15, lines 44-63; col. 7, lines 4-18), a detection chamber (fig. 1, ref. 6) with a flow front control feature such as channels in the opposing surface of the detection chamber (fig. 1, ref. 6; col. 17, lines 1-14; col. 17, line 55 to col. 18, line 67; col. 23, line 6-36), and a waste chamber (fig. 1, ref. 7; col. 7, lines 31-50; col. 20, line 42 to col. 21, line 24). The flow control features control the flow of the sample liquid in the detection chamber (see citations above). D1 also discloses hydrophobic and hydrophilic regions on the opposing surface as flow front controlling means (col. 18, line 28; col. 28, line 49).
- 2 Dependent claims 2-9 and 20 do not contain any features which, in combination with the features of any claim to which it/they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see document D1 as cited above and the corresponding passages cited in the search report.

Group IV:

Independent claim 17

- 3 D3 shows the closest prior art with respect to claim 18. It discloses:
A cartridge comprising a detection chamber with opposing surfaces and with a sensor surface, a waste chamber, and modules comprising a housing, an exit seal, and a plunger which is suitable to deliver a volume through the exit port (col. 5, line 10 to col. 6, line 47; col. 7, line 1 to col. 10, line 56; col. 13, line 20 to col. 14, line 29; col. 17 lines 11-22). The plunger comprises a piercing tip to pierce said seals.

- 3.1 D3 differs from subject-matter of claim 18 in that it does not disclose two filled chambers in combination with two seals. This difference solves the problem to enable processing of components in a module prior to expelling its content through an exit port for further analysis into said cartridge housing.
- 3.2 A person skilled in the art in search to find a solution to the obvious problem to process liquids prior to adding them to the analysis will be aware of the teaching of D5, which discloses:
A module and a method of delivering material from said modules comprising a housing, an exit seal, multiple prefilled chambers separated by penetrable barriers, a plunger and an input port between plunger and exit seal wherein the plunger is suitable to open the barriers and exit seal so as to transport fluids from one chamber to another and finally through the exit port (fig. 16a, b; page 21, line 10 to page 22, line 15).
- 3.3 As the features as described in document D5 providing the same advantages as in the present application, the skilled person would regard it as a normal design option to include this feature in the module described in document D3 in order to solve the problem posed.
- 3.4 Subject-matter of claim 17 thus lacks an inventive step (Article 33(3) PCT).

Independent claims 25, 30, 32 and 36

- 4 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 25, 30, 32 and 36 is not new in the sense of Article 33(2) PCT. The document D5 discloses (the references in parentheses applying to this document):
A module and a method of delivering material from said modules comprising a housing, an exit seal, multiple prefilled chambers separated by penetrable barriers, a plunger and an input port between plunger and exit seal wherein the plunger is suitable to open the barriers and exit seal so as to transport fluids from one chamber to another and finally through the exit port (fig. 16a, b; page 21, line 10 to page 22, line 15). D5 also discloses vertically disposed multiple chambers each separated by

penetrable barriers (part 2. The processing module, page 16). Furthermore, it discloses piercing tips as means to break said seals (page 4, line 29).

Dependent claims 28-32, 34 and 36-39

- 6 Dependent claims 28-32, 34 and 36-39 do not contain any features which, in combination with the features of any claim to which it/they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see document D1 as cited above and the corresponding passages cited in the search report.

Re Item VIII.

- 7 Claim 17 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved (ie. "flow front control feature", "detection surface"), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. Furthermore these feature relate to the use of device and not to the technical features necessary.
- 8 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D5 is not mentioned in the description, nor are these documents identified therein.
- 9 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 10 The features of the claim/s are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

December 1, 2005

-1-

CLAIMS:

1. A detection cartridge comprising:

a housing comprising an interior volume;

5 a sensor operably attached to the housing, the sensor comprising a detection surface;

a detection chamber located within the interior volume of the housing, wherein the detection chamber comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the
10 opposing surface comprises a flow front control feature that comprises one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface; and
a waste chamber located within the interior volume of the housing, the waste chamber in fluid communication with the detection chamber.

15

2. A cartridge according to claim 1, wherein the detection surface comprises an acousto-mechanical waveguide.

3. A cartridge according to claim 1, wherein the sensor comprises a surface
20 acoustic wave acousto-mechanical sensor.

4. A cartridge according to claim 1, wherein the flow front control feature comprises discrete structures protruding from and separated by a land area on the
25 opposing surface of the detection chamber.

5. A cartridge according to claim 1, wherein the flow front control feature comprises one or more channels in the opposing surface of detection chamber.

25

6. A cartridge according to claim 5, wherein at least one channel of the one or
30 more channels is oriented generally perpendicular to a longitudinal axis defined within the detection chamber between an input end and an output end of the waste chamber.

7. A cartridge according to claim 1, further comprising at least one pair of successive bands of hydrophobic material and hydrophilic material wherein each pair of successive bands extends across a width of the detection chamber.

5 8. A cartridge according to claim 1, wherein the flow front control feature comprises discrete structures protruding from and separated by a land area on the opposing surface of the detection chamber, one or more regions of hydrophobic material occupying a portion of the opposing surface, and one or more regions of hydrophilic material occupying a portion of the opposing surface.

10 9. A cartridge according to claim 1, wherein the flow front control feature comprises one or more channels in the opposing surface of detection chamber, one or more regions of hydrophobic material occupying a portion of the opposing surface, and one or more regions of hydrophilic material occupying a portion of the opposing surface.

15 10. A cartridge according to claim 1, further comprising absorbent material located within the waste chamber.

20 11. A cartridge according to claim 1, wherein the cartridge further comprises capillary structure located between the detection chamber and the waste chamber.

25 12. A cartridge according to claim 1, further comprising a vent that, when open, places the interior volume of the housing in fluid communication with ambient atmosphere around the cartridge.

13. A cartridge according to claim 12, wherein the vent is located in the waste chamber.

30 14. A cartridge according to claim 12, wherein the vent comprises a closure element.

15. A cartridge according to claim 1, further comprising a fluid monitor operably connected to the housing, wherein liquid located within the interior volume of the housing can be sensed by the fluid monitor.

5 16. A detection cartridge comprising:

a housing comprising an interior volume;

a sensor operably attached to the housing, the sensor comprising surface acoustic wave acousto-mechanical sensor;

10 a detection chamber located within the interior volume of the housing, wherein the detection chamber comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface comprises one or more channels formed therein;

a waste chamber located within the interior volume of the housing, the waste chamber in fluid communication with the detection chamber;

15 absorbent material located within the waste chamber; and
capillary structure located between the detection chamber and the waste chamber.

17. A detection cartridge comprising:

20 a cartridge housing comprising an interior volume;

a sensor operably attached to the cartridge housing, the sensor comprising a detection surface;

25 a detection chamber located within the interior volume of the cartridge housing, wherein the detection chamber comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface comprises a flow front control feature;

a waste chamber located within the interior volume of the cartridge housing, the waste chamber in fluid communication with the detection chamber;

30 one or more sealed modules, wherein each module of the one or more sealed modules comprises an exit port attached to the cartridge housing through one or more module ports that open into the interior volume of the cartridge housing, and wherein each module further comprises:

a module housing comprising an exit port and a sealed interior volume;
 an exit seal located over the exit port of the module; and
 a plunger located within the interior volume of the module housing,
 wherein the plunger is movable from a loaded position in which the plunger
 is distal from the exit port to an unloaded position in which the plunger is
 proximate the exit port;

wherein movement of the plunger towards the exit port opens the exit
 seal such that material from the interior volume of the module housing exits
 through the exit port into the interior volume of the cartridge housing;
 and further wherein the interior volume of at least one module of the one or
 more sealed modules comprises:

a first chamber comprising a liquid located therein;
 a second chamber located within the interior volume of the module
 housing, the second chamber comprising a reagent located therein; and
 an inter-chamber seal isolating the second chamber from the first
 chamber within the module housing;

wherein the first chamber, the inter-chamber seal, and the second
 chamber are located between the plunger and the exit seal;

wherein movement of the plunger towards the exit port opens the inter-
 chamber seal such that the liquid in the first chamber contacts the reagent in
 the second chamber.

18. A cartridge according to claim 17, further comprising a staging chamber within
 the interior volume of the cartridge housing, wherein the staging chamber is located
 upstream from the detection chamber, and wherein the module ports open into the
 staging chamber.

19. A method of moving sample material through the detection cartridge of claim 1,
 the method comprising:

providing a detection cartridge according to claim 1;
 delivering sample material into the interior volume of the housing of the
 detection cartridge, wherein the sample material flows into the detection chamber, and

wherein flow front progression of the sample material through the detection chamber and towards the waste chamber is controlled at least in part by the flow front control feature on the opposing surface within the detection chamber.

- 5 20. A method according to claim 19, wherein delivering sample material into the detection chamber comprises delivering the sample material into a staging chamber located within the interior volume of the housing, wherein the sample material flows from the staging chamber into the detection chamber.
- 10 21. A method according to claim 19, wherein detection cartridge further comprises absorbent material within the waste chamber, and wherein the absorbent material draws sample material into the waste chamber.
- 15 22. A method according to claim 19, further comprising capillary structure located between the detection chamber and the waste chamber, wherein the capillary structure draws sample material from the detection chamber.
- 20 23. A method according to claim 19, further comprising a vent that, when open, places the interior volume of the housing in fluid communication with ambient atmosphere around the cartridge, and wherein the method comprises opening the vent to control sample material flow through the detection chamber.
- 25 24. A method according to claim 23, wherein opening the vent comprises adjusting the size of the vent to adjust the rate of sample material flow through the detection chamber.
- 30 25. A sealed module comprising:
 a housing comprising an exit port and a sealed interior volume;
 an exit seal located over the exit port;
 a first chamber located within the interior volume of the housing, the first chamber comprising a liquid located therein;

a second chamber located within the interior volume of the housing, the second chamber comprising a reagent located therein;

an inter-chamber seal isolating the second chamber from the first chamber within the housing; and

5 a plunger, wherein the first chamber, the inter-chamber seal, the second chamber, and the exit seal are located between the plunger and the exit port, and wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port, and further wherein the plunger comprises a tip facing the inter-chamber seal,
10 wherein the tip pierces the inter-chamber seal to open the inter-chamber seal;

wherein movement of the plunger towards the exit port opens the inter-chamber seal such that the liquid in the first chamber contacts the reagent in the second chamber, and wherein further movement of the plunger into the unloaded position opens the exit seal such that the liquid and the reagent from the interior volume of the housing exit
15 through the exit port.

26. A module according to claim 25, wherein the first chamber and the second chamber comprise hermetically sealed compartments.

20 27. A module according to claim 25, wherein the plunger defines a portion of a volume of the first chamber when the plunger is in the loaded position.

28. A module according to claim 25, wherein the plunger mates with the exit port when the plunger is in the unloaded position.

25 29. A module according to claim 25, wherein the liquid in the first chamber comprises a water and the reagent in the second chamber comprises a hydrolyzable material.

30 30. A method of delivering materials using a sealed module of claim 25, the method comprising:
providing a sealed module according to claim 25;

moving the plunger towards the exit port of the sealed module to open the inter-chamber seal and force the liquid from the first chamber into contact with the reagent in the second chamber; and

5 moving the plunger towards the exit port to open the exit seal and expel the liquid and the reagent from the interior volume of the housing through the exit port.

31. A method according to claim 30, wherein the plunger comprises a tip that pierces the inter-chamber seal.

10 32. A module comprising:

a housing comprising an exit port and a sealed interior volume;

an exit seal located over the exit port;

a chamber located within the interior volume of the housing, the chamber comprising one or more reagents located therein;

15 a plunger movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; and

an input port in fluid communication with the chamber, wherein the input port enters the chamber between the plunger and the exit port when the plunger is in the loaded position;

20 wherein the plunger comprises a tip facing the exit seal and wherein the tip pierces the exit seal to open the exit seal, wherein movement of the plunger towards the exit port opens the exit seal such that material from the interior volume of the housing exits through the exit port.

25 33. A module according to claim 32, further comprising a seal closing the input port,

34. A module according to claim 32, wherein the plunger defines a portion of a volume of the chamber when the plunger is in the loaded position.

30

35. A module according to claim 32, wherein the plunger mates with the exit port when the plunger is in the unloaded position.

36. A method of delivering materials using a module according to claim 32, the method comprising:

providing a module according to claim 32;

5 delivering sample material comprising a liquid into the chamber through the input port, wherein the sample material contacts the reagent located within the chamber; and

moving the plunger towards the exit port to open the exit seal such that the liquid exits from the chamber through the exit port.